PCA UPDATE

UNEXPECTED DEATHS OF PATIENTS RECEIVING PATIENT-CONTROLLED ANALGESIA

November, 2001

Over the past several years, the Board's Patient Care Assessment (PCA) Committee has reviewed multiple reports of unexpected deaths of patients who were receiving patient-controlled analgesia. In some of the cases, analgesia was being used for post-operative pain management, while others involved patients being treated for management of other causes of chronic or acute pain. Most of the events occurred within the first ten hours of analgesia administration and many occurred during the late evening or night. The majority of the incidents involved women. Nearly all of the patients had medical conditions or physical traits, such as obesity, asthma, sleep apnea, or nasopharyngeal swelling, which potentially increased their risks for respiratory complications. The cause of death was never conclusively determined in any of these cases. However, oversedation, in some instances coupled with respiratory compromise, was considered to be a causal or contributing factor in some of the deaths.

In two incidents, questions were raised about whether potentially additive effects of intraoperative or supplemental medications, such as opioids, benzodiazipines, sedatives, hypnotics or antihistamines were adequately considered when the patient-controlled analgesia was ordered. Further, because many of the incidents occurred during the late evening or night, PCA Committee members questioned whether enough attention was paid to nighttime changes in patients' metabolic needs and nighttime medications when the analgesia was prescribed.

In none of the incidents described above, did the hospitals conclusively determine that the analgesia pump malfunctioned or that the patient received doses of narcotic in excess of what was ordered. However, this is an issue that should be carefully considered when investigating any incident involving a patient who develops respiratory compromise while receiving this method of analgesia. We assume that all hospitals have procedures for maintaining infusion pumps and that they provide ongoing training and education on the programming and operation of every model of infusion pump used for this purpose.

Corrective actions by the hospitals in response to many of these events included efforts to improve risk assessment of patients prior to initiating patient-controlled analgesia, and more frequent assessment and monitoring of all patients receiving this treatment, particularly those with potential risk for respiratory compromise. Hospitals also reviewed and improved their order forms for patient-controlled analgesia.

We bring these incidents to your attention to remind you of the risks associated with this form of analgesia, which is now widely used in hospitals and considered to be a relatively safe and effective method for pain management. Please review your policies, procedures, and standardized order forms to determine whether they provide for the following:

- adequate assessment by the prescribing physician of any potential risks for respiratory depression or compromise, and consideration of that risk when determining the loading and maintenance dosage for patient-controlled analgesia;
- consideration of intraoperative medications and other medications that the patient received or is receiving prior to calculating the loading or maintenance dosage for patient-controlled analgesia, including any opioids, benzodiazipines, sedatives, hypnotics or antihistamines;
- consideration of the patient's nighttime needs and nighttime medications when adjusting the analgesia, with special emphasis on continuous infusion rates;
- a requirement that the order form for patient-controlled analgesia not be filled by pharmacy unless all sections are completed;
- a system for double-checking the drug being used for analgesia, the pump setting, and the dosage;
- appropriate levels of assessment, monitoring, and documentation of vital signs, oxygen saturations, sedation levels, and degree of pain, particularly immediately following initiation of patient-controlled analgesia and during nighttime hours, including the use of apnea alarms on high risk patients;
- the immediate availability of oxygen for all patients receiving patient-controlled analgesia;
- the immediate availability of Narcan for emergency use in the event of potential oversedation; and
- if an adverse event occurs, procedures for determining whether the pump was functioning properly, and whether the concentration of the drug and rate of administration were as ordered.

Finally, the ability to recognize signs and symptoms of oversedation and to respond rapidly is crucial to those caring for patients receiving this form of analgesic treatment, as is the ability to distinguish overdosage from other possible causes of the adverse event, such as pulmonary, neurologic, or cardiovascular complications. We recommend that ongoing education be provided to medical and nursing staff about patient-controlled analgesia, including: associated risks; policies and procedures for administration; and recognition and treatment of signs and symptoms of complications.
